REMARKS/ARGUMENTS

1. Disposition of Claims

As required by 37 CFR 1.116, this amendment after final rejection complies with the requirements of that section, because it can be considered either to comply with any requirements of form expressly set forth in the previous Office Action or to present the rejected claims in better form for consideration on appeal. Claims 14-28 (minus claim 17) and claims 50-63 are pending in this application. Claims 14 and 18 have been amended to add a comma (claim 14) and strike the word "chronic" (claim 18) that is left over from when said claim depended from a canceled claim and was then amended to relate back to an appropriate claim that is pending. Claims 50 to 63 have been added, for which exact antecedent basis is found throughout the patent specification, for example, original claims 14-28 (minus claim 17) directed to methods for the treatment of a disease and paragraph [0031] defining the term "treatment", as further discussed below. No new matter has been added. Reexamination and reconsideration of the application are respectfully requested.

2. No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over any cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

3. New Claims 50-63

As discussed above, claims 50 to 63 have been added, for which exact antecedent basis is found throughout the patent specification, for example, original claims 14-28 (minus claim 17) directed to methods for the treatment of a disease and paragraph [0031] defining the term "treatment". The new claims add an additional feature "in need of said treatment" from

paragraph [0031] in the patent specification to substitute for the additional feature "having been determined to express an elevated level of IL-17 compared to a healthy individual" that was added in claims 14-28 (minus claim 17) to distinguish successfully from Chirica et al. (US 6,756,481).

The issue is whether the content of the "amendment" to original claims 14-28 directed to methods for the treatment of a disease, namely, the addition of the feature "in need of said treatment" from paragraph [0031], thus creating new claims 50-63, is new matter. Under MPEP 2163.07, amendments to the application which are supported in the original description are not new matter. Indeed, there is exact antecedent basis for the feature "in need of said treatment" from paragraph [0031]. Paragraph [0031] says:

> The terms "**treat**" or "**treatment**" refer to both therapeutic treatment and prophylactic or preventative measures, wherein the object is to prevent or slow down (lessen) an undesired physiological change or disorder. For purposes of this invention, beneficial or desired clinical results include, but are not limited to, alleviation of symptoms, diminishment of extent of disease, stabilized (i.e., not worsening) state of disease, delay or slowing of disease progression, amelioration or palliation of the disease state, and remission (whether partial or total), whether detectable or undetectable. "Treatment" can also mean prolonging survival as compared to expected survival if not receiving treatment. **Those in need of treatment** include those already with the condition or disorder as well as those prone to have the condition or disorder or those in which the condition or disorder is to be prevented. [Emphases added.]

Paragraph [0031] defining the term "treatment" indicates that those in need of treatment mean those already with the condition or disorder or disease. Thus lies the source for the phrase "in need of said treatment" to be incorporated into the treatment claims. As the amendment to the application is supported in the original description, the conclusion is that the content of the "amendment" to original claims 14-28 directed to methods for the treatment of a disease, namely, the addition of the feature "in need of said treatment" from paragraph [0031], thus creating new claims 50-63, is not new matter.

The issue is whether the content of the "amendment" to original claims 14-28 directed to methods for the treatment of a disease, namely, the addition of the feature "in need of said treatment" from paragraph [0031], thus creating new claims 50-63, meets the written description

requirement. Under MPEP 2163.06, lack of written description is an issue that will arise if the content of the amendment to a claim is new matter. As discussed above, the content of the "amendment" to original claims 14-28 directed to methods for the treatment of a disease is not new matter. This is because there is exact antecedent basis for the feature "in need of said treatment" from paragraph [0031] in the patent specification. As the content of the "amendment" to original claims 14-28 directed to methods for the treatment of a disease, namely, the addition of the feature "in need of said treatment" from paragraph [0031], thus creating new claims 50-63, is not new matter, no issue under the written description requirement would arise.

The issue is whether the new claims by adding an additional feature "in need of said treatment" from paragraph [0031] in the patent specification to substitute for the additional feature "having been determined to express an elevated level of IL-17 compared to a healthy individual" that was added in claims 14-28 (minus claim 17) to distinguish from Chirica et al. (US 6,756,481) actually themselves distinguish from Chirica et al.. According to MPEP 2131, to anticipate a claim, a reference must teach every element of the claim. The feature "in need of said treatment" is missing from Chirica et al. Chirica et al. describes methods of administering an antagonist of IL-23 to a subject mammal in need of treatment of a disease characterized by elevated expression of IL-23. Chirica et al. does not suggest the feature of administering an antagonist of IL-23 to a subject mammal in need of treatment of a disease characterized by elevated expression of IL-17. This is because, as disclosed in the patent specification paragraph [0039], the invention is based on the recognition that IL-23 induces IL-17 production in immune cells and that IL-23 antagonists are capable of inhibiting this process. The feature "in need of said treatment" thus distinguishes from prior art uses of antagonists of IL-23. The case law is in accord. *Jansen v. Rexall Sundown, Inc.*, 68 USPQ2d 1154 (Fed. Cir. 2003) stands for the proposition that in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof", during the prosecution of which the patentee added the phrase "a human in need thereof" to distinguish from other prior art methods related to anemia per se, the claim is properly interpreted to mean that the vitamin preparation must be administered to a human with a recognized need to treat or prevent pernicious anemia. Similarly, here, in a claim directed to a method of treating a disease

characterized by elevated expression of IL-17 in humans by administering an antagonist of IL-23 to a human "in need of said treatment", to distinguish from other prior art methods related to treating a disease characterized by elevated expression of IL-23, the claim is properly interpreted to mean that the antagonist of IL-23 must be administered to a human with a recognized need to treat a disease characterized by elevated expression of IL-17. Consequently, Chirica et al. does not teach every element of any of the new claims. The element of "in need of said treatment" is missing. The conclusion is that Chirica et al. does not anticipate the new claims.

4. Claims 14-28 (Minus Claim 17)

Claims 14-28 (minus claim 17) previously added an additional feature "having been determined to express an elevated level of IL-17 compared to a healthy individual" from paragraphs [0067], [0070], and [0072] in the patent specification to distinguish successfully from Chirica et al. (US 6,756,481). The issue is whether the content of the amendment to original claims 14-28, namely, the addition of the feature "having been determined to express an elevated level of IL-17 compared to a healthy individual" from paragraphs [0067], [0070], and [0072], is new matter. Under MPEP 2163.07, amendments to the application which are supported in the original description are not new matter. As discussed below, because the amendment to the application is supported in the original description, the conclusion is that the content of the amendment to original claims 14-28, namely, the addition of the feature "having been determined to express an elevated level of IL-17 compared to a healthy individual" from paragraphs [0067], [0070], and [0072], is not new matter.

The issue is whether the content of the amendment to original claims 14-28, namely, the addition of the feature "having been determined to express an elevated level of IL-17 compared to a healthy individual" from paragraphs [0067], [0070], and [0072], meets the written description requirement. Under MPEP 2163.06, lack of written description is an issue that will arise if the content of the amendment to a claim is new matter. As discussed below, the content of the amendment to original claims 14-28 is not new matter. This is because there is ample antecedent basis for the feature "having been determined to express an elevated level of IL-17 compared to a healthy individual" from paragraphs [0067], [0070], and [0072] in the patent specification. As the content of the amendment to original claims 14-28, namely, the addition of the feature "having been determined to express an elevated level of IL-17 compared to a healthy

individual" from paragraphs [0067], [0070], and [0072], is not new matter, no issue under the written description requirement would arise.

The case law rejects the notion that a later claim must use the exact, literal language of the earlier disclosure. Federal Circuit decisions confirm that "ipsis verbis", or literal, disclosure is unnecessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art the inventor had possession of the subject matter in question.

In *Moba B.V. v. Diamond Automation, Inc.*, 66 USPQ2d 1429 (Fed. Cir. 2003), the panel's *per curiam* opinion discussed the written description doctrine. *Moba* involved patents for high-speed egg processing machines. The jury found the patents not invalid both for written description and enablement. On appeal, the accused infringer argued that if the scope of a claim covered lifting eggs from a moving conveyor, the claim had to be invalid for written description because the patent's specification did not disclose such a conveyor mechanism. The opinion explains that the written description doctrine of § 112 ¶ 1 was originally used synonymously with § 132, and has since been applied two different ways by the court.

First, the doctrine has been applied with the purpose of preventing a patentee from later claiming something they did not invent earlier, but, in *Moba*, the accused infringer made no allegation that the patent's specification did not show possession of a later-filed claim.

Second, the doctrine has been applied to require not a particular form of disclosure but a disclosure such that a person of ordinary skill could determine from the specification that the inventor possessed the invention at the time of filing.

The egg processing claims required three "guiding" steps in which the eggs were lifted to various locations. The accused device performed all three guiding steps and used a moving conveyor. The patent specification described every element of the claims in sufficient detail so that one of one of ordinary skill in the art would recognize that the inventor possessed the invention at the time of filing. The contention that the patent did not adequately disclose lifting eggs from a moving conveyor merely revived the non-infringement argument in the cloak of a validity challenge. Because substantial evidence supported the jury's finding of possession by the patentee, the written description doctrine did not apply.

In *Pandrol USA, LP v. Airboss Railway Products, Inc.*, 76 USPQ2d 1524 (Fed. Cir. 2005), the Federal Circuit affirmed the district court's ruling that no reasonable juror could find that the patent at issue failed to satisfy the written description requirement of 35 USC § 112.

The technology involved in the patent at issue was a railroad track fastening system, particularly "a rail seat assembly that resists erosion of the concrete rail tie by interposing an abrasion-resistant plate and a layer of adhering material between the raid pad and the rail." The district court declined to invalidate the patent's claims on the basis of failure to meet the written description requirement "because the specification includes sufficient disclosure to support the claim limitations that include the terms 'adhering material' and 'sole means,' both of which were added by amendment during prosecution."

The Federal Circuit stated that, in a first appeal of this case, the court concluded that "a closed cell foam pad is an 'adhering material.'" The Federal Circuit continued that, in a second appeal of this case, the court reiterated, "[b]oth the abstract and the preferred embodiment make clear that a gasket between the rail plate and rail tie, in and of itself, constitutes an 'adhering material.'" The Federal Circuit acknowledged that 'the district court [from which the appeal at issue was taken] properly reached the same conclusion" when making its summary judgment determination.

The Federal Circuit then called attention to several passages in the original specification and original abstract. The first section cited from of the original specification stated, "[p]referably the abrasion plate may be adhered to the surface of the concrete tie to ensure that ingress of abrasive particles and water onto the surface of the rail tie is avoided." The next section explained an effective seal was essential, and described epoxy or a HDPE closed cell foam gasket as alternatives for creating the seal. A third portion mentioned, "[t]he plate 10 may be bonded by adhesive (epoxy resin adhesives are preferred) to the tie 1 or an HDPE closed cell foam of 1.5 mm thickness of the same size and shape as plate 10 is fitted between the plate 10 and tie 1." The original abstract also revealed that : [t]he plate may be bonded to the rail tie or a resilient gasket can be interposed between the rail tie and the plate."

The Federal Circuit concluded the aforementioned passages demonstrated "that one way of providing an effective adhesive seal between the plate and the concrete rail tie is a closed cell

foam pad." The court therefore found the claimed "adhering material" was described with "sufficient detail to show possession of the full scope of the invention."

The court next addressed the "sole means" limitation of claim 1, which required the adhering material to be "the 'sole means' for adhering the abrasion resistant plate to the rail ties." There was some question as to whether the discloses adherents were the sole means for performing the adhering function based on a disclosed mechanical clamping system for locking and holding the system in place. However, the court noted, "the sole means limitation refers to the specific bonding of the rail tie to the rail pad to prevent erosion of the concrete rail tie with a watertight seal." The court then held, "[t]he district court correctly discerned that the specification provides adequate distinctions between clamping and adhering to show possession of the 'sole means' aspect of the claimed invention." Consequently, the Federal Circuit affirmed the district court's determination that the patent at issue satisfied the written description requirement.

In *Kao Corp. v. Unilever United States, Inc.*, 78 USPQ2d 1257 (Fed. Cir. 2006), Unilever appealed a patent infringement judgment in favor of Kao. Kao owned the patent at issue directed to a certain type of skin-care product to remove keratotic plugs (i.e., "blackheads") from the skin. Unilever manufactured the allegedly infringing Pond's Clear Pore Strips.

Claim 1 of the patent at issue recites:

> A method for removing keratotic plugs from skin with a cosmetic article, which comprises:
>
> *wetting the skin or said cosmetic article*; applying onto the skin said cosmetic article; and *peeling off said cosmetic article after drying*; wherein said cosmetic article comprises:
>
> i) a substrate selected from the group consisting of woven cloth, non-woven cloth and a plastic film; and
>
> ii) on said substrate, a layer comprising a copolymer, in an amount effective to remove keratotic plugs, wherein said copolymer is a poly(alkyl vinyl ether/maleic acid) copolymer or a polyalkylvinyl ether/maleic anhydride) copolymer.

The italicized language, added by amendment during patent prosecution, was at issue in the case. The written description contained eight examples regarding the preparation and use of

liquid or semi-solid copolymer preparations. The examples did not discuss drying the liquid or semi-solid copolymer onto a substrate, but rather described applying them directly to the face. Furthermore, the specification did not define the term "cosmetic article" but did mention that "[t]he keratotic plug remover according to this invention may take a form of a poultice using cotton cloth, rayon cloth, tetron cloth, nylon cloth, either woven or non-woven, or using a plastic film sheet. beside pack preparations." The specification also taught that "[t]he manner of removing keratotic plugs by the use of the keratotic plug remover of the invention is the same as the manner of using ordinary packs and poultice. Namely, when a pack preparation is used, it is first applied to the part of the skin which has keratotic plugs, particularly likely to the nose, chin, and forehead, and after dried, it is peeled off."

In Kao's suit for injunctive relief against Unilever, the district court held a bench trial and determined that the specification of the patent at issue adequately described the step of wetting the skin or a "cosmetic article" for the purposes of 35 USC § 112 ¶ 1.

On appeal, the Federal Circuit reviewed the district court's written description finding for clear error. The district court offered two reasons for its written description finding: (1) that the phrase "wetting the skin or said cosmetic article" appropriately informed those of ordinary skill in the art that either the skin or the "cosmetic article" should be wetted prior to application and (2) that the wetting step was so straightforward that a detailed description in the specification was unnecessary. Unilever challenged the second rationale on appeal.

The Federal Circuit rejected Unilever's argument that the only embodiments in the specification are already wet and that, as a result, the references to drying are insufficient to alert a person having ordinary skill in the art to what the wetting step, "wetting the skin or said cosmetic article," actually entails. Clear error in the district court's decision could not be found. Accordingly, the Federal Circuit upheld the district court's written description decision.

Here, as in *Moba*, the patent specification describes every element of the claims in sufficient detail so that one of one of ordinary skill in the art would recognize that the inventor possessed the invention at the time of filing. The amended claims require a "measuring" step, in which a human subject is determined to express an elevated level of IL-17 compared to a healthy individual. Paragraphs [0067], [0070], and [0072] of the specification describe the elements of these claims. The contention that the patent did not adequately disclose the measuring step

revives the argument that preceded the insertion of the material by amendment into the body of the application to replace an incorporation by reference statement in paragraphs [0067], [0070], and [0072]. The supposition that there is no support for the measuring step as a preliminary step to the administration of an antagonist of IL-23 is incorrect. A person of ordinary skill in the art would understand the preamble of original claim 14 describing a method for the treatment of a disease characterized by elevated expression of IL-17 to involve the measuring step in which a human subject is determined to express an elevated level of IL-17 compared to a healthy individual as a preliminary step to the administration of an antagonist of IL-23.

Here, as in *Pandrol*, the specification includes sufficient disclosure to support the claim limitations that include all the terms. The measuring step appears literally in paragraphs [0067], [0070], and [0072] of the specification sufficient to teach one skilled in the art what a measuring step that precedes administration of an IL-23 antagonist to treat an IL-17 disease might occasion. The preliminary step is capable of being understood in the context of the patent specification in which paragraph [0039] emphasizes that "the invention is based on the recognition that IL-23 induces IL-17 production in activated [immune] cells, and that IL-23 antagonists are capable of inhibiting this process." This description teaches the distinction between a new use for an IL-23 antagonist in treating an IL-17 disease and its old use in treating an IL-23 disease. The originally filed disclosure at paragraph [0039] in combination with original claim 14 would allow one skilled in the art to discern that the IL-17 measuring step preliminary to the administration of an IL-23 antagonist in a method for the treatment of an IL-17 disease was part of the very definition of the invention.

Finally, here, as in *Kao*, the preliminary step is so straightforward that a detailed description in the specification is unnecessary. It is clear what the invention is NOT. From paragraph [0039] in conjunction with original claim 14, it does not concern the treatment of an IL-23 disease comprising the administration of an IL-23 antagonist, but the treatment of an IL-17 disease. The references to paragraphs [0067], [0070], and [0072] are sufficient to alert a person having ordinary skill in the art to what the measuring step, "having been determined to express an elevated level of IL-17 compared to a healthy individual," might actually entail. A person of ordinary skill in the art would appreciate the process of treating a disease characterized by

elevated expression of IL-17, as described in the written description, to involve determining a human subject to express an elevated level of IL-17 compared to a healthy individual.

In conclusion, because the amendment to the application is supported in the original description, the result is that the content of the amendment to original claims 14-28, namely, the addition of the feature "having been determined to express an elevated level of IL-17 compared to a healthy individual" from paragraphs [0067], [0070], and [0072], is not new matter; and no issue under the written description requirement would arise.

CONCLUSION

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Please charge any fees that may be required, or credit overpayment to Deposit Account No. 07-1700 (referencing GNE-0125A).

Respectfully submitted,

Date: April 22, 2008

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